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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/258,132

02/26/1999

PHILIP GOELET

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3407

7590

05/12/2003

David A. Kalow, Esq.
KALOW, SPRINGUT & BRESSLER, LLP
488 Madison Ave.
19th Floor
New York, NY 10022

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/258,132	GOELET ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64 and 66-71 is/are allowed.
- 6) ☒ Claim(s) 60-63 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1634

1. This action is in response to the amendment filed March 24, 2003. Applicants amendments and arguments have been fully considered but are not persuasive to overcome all grounds of rejection. This action is made final.
2. The CRF and paper copy of the Sequence Listing filed on March 24, 2003 has been entered.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-63 and newly added claim 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 60-63 are directed to a method in which either one or more unique oligonucleotide primers are attached to a unique affinity moiety which specifically binds to a discrete position on a solid support or a plurality of unique oligonucleotide primers are attached to discrete positions of a solid support and then the target nucleic acid is added and to form a duplex and extension occurs on the immobilized primers. Additionally, claim 63 further includes a step of sorting the extended primers by affinity capture. However, the specification does not provide support for these concepts. Applicants point to page 27, lines 12-24, pages 29 and 30 and page 31, lines 25-35 as providing support for these new claims. Upon thorough review of specification, particularly the cited portions of the specification, the claimed subject matter was found to be insufficiently described to reasonably

Art Unit: 1634

convey to the skilled artisan that applicant was in possession of the claimed invention at the time of filing. While the specification describes attaching one or more affinity moieties to the primers to permit affinity separation (page 27, lines 12-24), and describes the affinity moiety as being a complementary nucleic acid sequence (page 27, lines 19-24), the specification does not describe the concept of attaching the primers or the affinity moieties to discrete positions on a solid support. From the specification it is clear that the intent of the immobilization on the solid support and the attachment of affinity moieties is to achieve separation of the extended primer from the unincorporated labeled terminators. Page 29, line 31 through page 30, line 3, teach the concept of simultaneous analysis of more than one oligonucleotide using more than one affinity group. This teaching, however, is not equivalent to the attachment of a plurality of oligonucleotide primers or a plurality of affinity moieties to "discrete positions" of a solid support. This concept of "discrete positions" has not been described in the specification and does not appear to have been part of the original inventive concept. The claims, as written, read on methods using oligonucleotide array technology which was not described in the specification. The specification only teaches the general concept that multiple oligonucleotide primers each with a different affinity moiety can be used to detect multiple target nucleotides. However, the specification does not teach the more complex concept of specifically arranging the oligonucleotides and/or affinity moieties to discrete positions on a solid support and determining the identity of a target nucleotide by determining its position on a solid support. Claim 63 is particularly unsupported by the specification because the specification contains no description of sorting the extended primers by affinity capture and then determining the

Art Unit: 1634

identity and location of the terminator to determine the identity of the bases at a plurality of sites. These concepts are unobvious extensions of the teachings that a different affinity moiety can be used to capture a plurality of different primers because the teachings contain no reference using the affinity moieties to sort the primers or to capture the primers at specific locations on a solid support as a means for identification of the target bases. Therefore, for the reasons, given above, the claims introduce new matter into the specification.

RESPONSE TO ARGUMENTS:

In the response filed March 24, 2003, Applicants state that the specification teaches the simultaneous analysis of oligonucleotides and points to pages 29-30 of the specification as providing support for the concept of attaching a plurality of oligonucleotide primers or a plurality of affinity moieties to discrete positions of a solid support. It is stated that one of skill in the art would recognize that in order to analyze the oligonucleotides simultaneously, the oligonucleotides would have to be separately affinity separated at distinct positions. These arguments have been fully considered but are not persuasive. Pages 29-30 of the specification state: "More than one oligonucleotide can be separated from the terminator reagent and analyzed simultaneously if more than one affinity group is used. This permits the analysis of several nucleic acid species or more nucleic acid sequence information per extension reaction." Thus, while the specification discusses the concept of simultaneous analysis of multiple oligonucleotides, the specification does not teach that this may be achieved by attaching the affinity group or oligonucleotide primer to discrete positions on a solid support. There is more than one means by which multiple oligonucleotides can be simultaneously

Art Unit: 1634

analyzed. For example, the specification teaches the attachment of the oligonucleotide primers to beads/microspheres. Thus, one could contemplate methods in which a first set of beads having immobilized thereon oligonucleotide primer A is combined with a second set of beads having immobilized thereon oligonucleotide primer B and the first and second set of beads are simultaneously analyzed to allow for the simultaneous analysis of a plurality of oligonucleotides. The concept of attaching of oligonucleotides to distinct beads is different from the concept of attaching oligonucleotides to discrete positions on a solid support. Further, the specification discusses the use of oligonucleotide primers which are labeled with distinct fluorophores. Thereby, one could also contemplate methods in which the labeling of distinct oligonucleotide primers with distinguishable fluorophores would allow for the simultaneous analysis of multiple oligonucleotides. While such methods might be obvious in view of the teachings in the specification, this is not the criteria by which to determine whether the specification as originally filed provides support for the invention now claimed. Thereby, it is maintained that the specification as originally filed does not provide support for the specific embodiment of methods in which the affinity moiety or oligonucleotide primer is bound to a discrete position on a solid support.

Applicants further traverse this rejection by stating that the term "sort" is defined by Webster's dictionary to mean "to arrange according to characteristics: CLASSIFY." Thereby, Applicants assert that the originally filed specification provides basis for the concept of separately affinity separating more than one oligonucleotide at distinct positions. However, the concept of classifying is very broad and there are many ways in which one could sort or classify oligonucleotides.

Art Unit: 1634

Yet, there are no specific teachings in the specification that Applicants contemplated sorting the extended primers by affinity capture and then determining the identity and location of the terminator to determine the identity of the bases at a plurality of sites. As discussed above, the specification as originally filed does not provide basis for the specific concept of using the affinity moieties to sort the primers or to capture the primers at specific locations on a solid support as a means for identification of the target bases.

5. Claims 60-63 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60-63 and newly added claim 65 are indefinite over the recitation of "discrete position" and "defined positions" because these phrases make the claims unclear as to whether each primer or affinity moiety is attached at a specific and unique location on a solid support or whether a discrete position includes a spot in a dot blot, for example, as shown in Figure 8 of the specification, wherein the dot blot contains an entire reaction mixture and not just an individual oligonucleotide primer.

RESPONSE TO ARGUMENTS:

In the response filed March 24, 2003, Applicants traverse this rejection by stating that one of ordinary skill in the art would readily understand what was intended to be meant by discrete positions and defined positions and that these phrases are clear and unambiguous. This response states applicants opinion but does not address the actual grounds of rejection. Applicants have not cited any passages from the specification as to providing a clear definition as to what is intended to be

Art Unit: 1634

encompassed by discrete and distinct positions. The rejection is maintained for the reasons stated above.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claim 65 is indefinite over the recitation of "wherein the affinity moiety of each unique oligonucleotide primer" because this phrase lacks proper antecedent basis. While the claim previously refers to "each different oligonucleotide primer", the claim does not previously refer to "each unique oligonucleotide primer". Furthermore, the phrase "the discrete positions on the solid support" lacks proper antecedent basis because the claim does not previously refer to discrete positions on a solid support.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1634

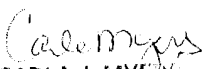
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

May 6, 2003


CARLA J. MYERS
PRIMARY EXAMINER